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10/813,098

03/31/2004

Odile Aubrun-Sonneville

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EXAMINER

KAROL, JODY LYNN

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/813,098	<b>Applicant(s)</b> AUBRUN-SONNEVILLE ET AL.	
	<b>Examiner</b> Jody L. Karol	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to the amendments and remarks submitted on 3/5/2008. Claims 13-14 have been amended. Claims 1-17 are pending and examined on the merits herein.

#### ***Response to Remarks - Summary***

1. In view of Applicants' amendments, the objection to the specification is herein withdrawn.
2. Upon further consideration and in view of Applicants' remarks and amendments, the rejection of claims 11, 13-14, and 17 as indefinite under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, the rejection is herein withdrawn.
3. The following rejections are herein withdrawn in view of the new grounds of rejection of these claims under 35 U.S.C. 103(a) under *Morchäuser et al.* (EP 1 069 142):
  - a. claims 1-7, 11, 12, 15, and 16 under U.S.C. 35 102(b) over *Morchäuser et al.* (EP 1 069 142);
  - b. claims 1-17 under 35 U.S.C. 103(a) over *Morchäuser et al.* (EP 1 069 142);
  - c. claims 1-17 under 35 U.S.C. 103(a) over *Morchäuser et al.* (EP 1 069 142) in view of *Lennon et al.* (US 2003/0157047);

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d. claims 1-17 under 35 U.S.C. 103(a) over Lennon et al. (US 2003/0157047);

Applicants' arguments pertaining to these rejections are moot in view of new grounds of rejection. Applicants' arguments that the prior art does not suggest the present invention are addressed in the new grounds of rejection presented below.

4. The rejection of claims 1-17 on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-5, 22-27, and 29-49 of US 6,905,674 B2 are herein withdrawn in view of the new grounds of rejection of these claims on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-5, 22-27, and 29-49 of US 6,905,674 B2 in view of Hoeffkes et al. (US 4,919,923).

5. The rejection of claims 1-10 and 12-17 on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-19 of copending Application 10/813,013 are herein withdrawn in view of the new grounds of rejection of these claims on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-19 copending Application 10/813,013 in view of Hoeffkes et al. (US 4,919,923).

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6. The following rejections and/or objection are either reiterated or newly applied.

They constitute the complete set of rejections and/or objections presently being applied in the instant application.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 22-27, and 29-49 of U.S. Patent No. 6,905,674 B2 in view of Hoeffkes et al. (US 4,919,923).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim compositions suitable for topical application that comprise an oily phase dispersed in an aqueous phase and a non-cross-linked

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amphiphilic copolymer comprising of (a) acrylamido-2-methylpropanesulfonic acid (AMPS) units and (b) units of formula (II) in the instant claims (which is analogous to formula (3) of the patented claim 24). The claims also claim methods of protecting the skin, lips, or hair by applying the composition.

The only significant difference between the instant claims and the patented claims is that the instant claims additionally require the presence of a wax. However, claim 46 of the patented claims indicates that the composition further comprises a cosmetic adjuvant selected from ingredients commonly employed in the cosmetic or dermatological field. Furthermore, claim 47 of the patented claims indicates that the composition can be a wax/aqueous phase dispersion.

Hoeffkes et al. teach that viscosity and rheological behavior are important factors in the stability and performance of oil-in-water emulsions, and that cosmetic creams often contain consistency-generating (thickening) components such as waxes to contribute to the stability of the emulsion (see column 1, lines 15-23). Suitable waxes used in oil-in-water emulsions include carnauba wax, beeswax, mineral wax, and polyethylene wax, etc. (see column 2, lines 44-53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ a wax component as taught by Hoeffke et al. in the composition of the patented claims. One of ordinary skill in the art would have been motivated to so in order to increase the viscosity and stability of the composition.

Other differences between the instant claims and the patented claims are that the patented claims do not include specific weight percentages for the oily phase and the

wax component and they do not claim specific properties for the wax, or the composition such as stability or viscosity. However, it would be within the purview of the skilled artisan to optimize the weight percentage of the components. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. *In re Aller*, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

Furthermore, the properties such as viscosity would obviously be present in the composition taught by the patented claims in view of Hoeffke et al. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties the applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The patented claims also do not claim that the composition is surfactant-free as claimed in the instant claim 11, but only claim 46 claims that a surfactant may be present as a cosmetic adjuvant. Therefore, compositions without surfactant are considered within the scope of the patented claims.

2. Claims 1-10 and 12-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/813,013.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim the identical composition, and overlapping methods of use for the composition, except that the instant claims require a wax component and the co-pending claims require a lipophilic emulsifier.

Hoeffkes et al. teach that viscosity and rheological behavior are important factors in the stability and performance of oil-in-water emulsions, and that cosmetic creams often contain consistency-generating (thickening) components such as waxes to contribute to the stability of the emulsion (see column 1, lines 15-23). Suitable waxes used in oil-in-water emulsions include carnauba wax, beeswax, mineral wax, and polyethylene wax, etc. (see column 2, lines 44-53).

However, it would have been obvious to one of skill in the art at the time of the invention was made to add a suitable wax component as taught by Hoeffkes et al. to the composition of the co-pending claims. One of ordinary skill in the art would have been motivated to do so in order to increase the viscosity and stability of the composition.

Other differences between the instant claims and the co-pending claims are that the patented claims do not include specific weight percentages for the oily phase and the wax component. Again, it is within the purview of the skilled artisan to determine an optimum working range for the components.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morschäuser et al. (EP 1 069 142) in view of Hoeffkes et al. (US 4,919,923). US 6,645,476 B1 is used as the English language equivalent of EP 1 069 142.

The instant claims 1-17 are directed towards topical compositions and methods of use, where the composition comprises an oily phase dispersed in an aqueous phase, at least one wax, and at least one non-crosslinked amphiphilic polymer. The polymer comprises from (a) 80 to 99 mol% of 2-acrylamido-2-methylpropane-sulphonic acid (AMPS) unit of formula (I), and (b) 1 to 20 mol% of units of formula (II) in which n and p, independently of each other, denote 0 to 24, with  $n+p < 25$ ;  $R_1$  is a hydrogen or linear or branched alkyl radical containing from 1 to 6 carbon atoms, and  $R_2$  denotes a linear or branched alkyl radical containing from 6 to 30 carbon atoms.

Morschäuser et al. teaches cosmetic compositions containing water-soluble polymers (see abstract). In a preferred embodiment, the polymer is a copolymer of the following macromonomers:

A) esters of (meth)acrylic acid with alkyl ethoxylates with 5 to 80 ethoxylation (EO) units; and

B) AMPS, or sodium and ammonium salts thereof,

wherein "A" is preferably present in 10 to 20 mol % as claimed in the instant claims 1-17 (see column 3, lines 23-33 and column 4 lines 6-8). Morschäuser et al. further teaches that the suitable macromonomers "A" are esters of (meth)acrylic acid with ( $C_{10}$ - $C_{22}$ )-fatty alcohol polyglycol ethers with varying amounts of EO units and  $C_{11}$ -oxo alcohol polyglycol ethers with 8 EO units as claimed in the instant claims 4-5 (see

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column 3, lines 36-59). In addition, the polymers are neutralized with  $\text{NH}_3$  as claimed in the instant claim 2 (see column 11, lines 19-20). Morschäuser et al. also teaches that the polymer is present in emulsions ranging from 0.05 to 10% by weight, which overlaps with the instant claim 6 (see column 5, lines 52-56). Morschäuser et al. additionally teaches that the polymers generally have number-average molecular weight of from 1,000 to 200,000,00 g/mol (see column 4, lines 12-15). Morschäuser et al. teach that the compositions can be water-in-oil emulsions or oil-in-water emulsions, and that the emulsions may also contain waxes as claimed in the instant claims 1-17 (see column 9, lines 14-15 and 27-32). The oily phase present in the emulsion ranges from 5 to 95% by weight, and preferably from 15 to 75% by weight as claimed in claim 7 (see column 9, 45-47). The composition may also be free of additional emulsifiers as claimed in the instant claim 11 (see column 5, lines 38-40). The emulsions are cosmetic preparations such lotions, creams, and ointments, and therefore suitable cosmetic or dermatological compositions as claimed in claim 12 (see column 5, lines 48-51). In a specific embodiment, Morschäuser et al. teach an o/w emulsion comprising 0.5% by weight of a non-crosslinked amphiphilic polymer comprising (a) AMPS neutralized with  $\text{NH}_3$  and (b) Genapol® UD-80 (esters of (meth)acrylic acid with  $\text{C}_{11}$ -oxo alcohol polyglycol ethers with 8 EO units) (see column 18, lines 56 to column 19, line 16 and column 11, Example 2).

Morschäuser et al. does not explicitly teach a composition suitable for topical application comprising an o/w emulsion that comprises a wax component in addition to the amphiphilic polymer as claimed, or compositions that do not additionally comprise a

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surfactant. Morschäuser et al. also does not teach weight percentages for the wax components, or specific wax components as claimed in the instant claims 8-10.

Morschäuser et al. also does not specifically describe methods for using the compositions as claimed in the instant claims 13-14 or properties of the compositions such as stability and viscosity as claimed in the instant claims 15-16. Lastly, Morschäuser et al. teaches the polymers' weight in terms of number-average molecular weight instead of weight-average molecular weight as claimed in the instant claim 17.

Hoeffkes et al. teaches that viscosity and rheological behavior are important factors in the stability and performance of oil-in-water emulsions, and that cosmetic creams often contain consistency-generating (thickening) components such as waxes to contribute to the stability of the emulsion (see column 1, lines 15-23). Suitable waxes used in oil-in-water emulsions include carnauba wax, beeswax, mineral wax, and polyethylene wax, etc. (see column 2, lines 44-53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a wax component as suggested by Morschäuser et al. and taught by Hoeffkes et al., to o/w emulsion compositions comprising the amphiphilic polymer as generally taught by Morschäuser et al. One of ordinary skill in the art would have been motivated to add a wax in order to adjust the viscosity of compositions formulated using the guidance provided by Morschäuser et al. The determination of the optimal weight percentages of the wax component by routine optimization is obvious as being within the purview of skilled artisan, absence a showing a criticality of said weight percentage ranges. One of ordinary skill in the art would have been motivated to optimize the

weight percentages of the wax in order to achieve a stable topical composition with the desired viscosity. The optimization of the result-effective parameter (i.e. weight percentage ranges) is considered obvious as being within the purview of skilled artisan.

Furthermore, the optimized compositions taught by Morschäuser et al. would obviously possess the properties as claimed in the instant claims 15-16. "Products of identical chemical composition cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties the applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In regards to the instant claims 13-14, Morschäuser et al. teaches that the emulsions are preferably cosmetic compositions such as shampoos, shower gels, foam baths, lotions, creams, and ointments (see column 5, lines 48-51). It would be obvious to one of ordinary skill in the art at the time of the invention to use the compositions of Morschäuser et al. in the care of, protection of, make-up of the skin, sensitive skin, lips, or hair by applying the composition to the skin, sensitive skin, lips, or hair. One of ordinary skill in the art would have been motivated to do this because it obvious to use a composition for its intended use.

In regards the instant claim 17, the polydispersity of a polymer has a large effect on the comparison of number-average versus weight-average molecular weight. Thus, absence evidence to the contrary, the number-average molecular weight of the polymer

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taught by Morschäuser et al. is considered to overlap with the weight-molecular range as claimed.

Thus, the invention as whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

### ***Response to Arguments***

9. Applicants' arguments that a *prima facie* case of obviousness does not exist because the compositions of the instant invention demonstrate unexpected results have been fully considered, but were not found persuasive.

The Applicants argue that the oil-in-water emulsions that do not include waxes, but are otherwise identical to the compositions as recited in claims 1 have inferior stability. Applicants specifically cite the example provided on page 36, line 23 to page 37, line 2. The example is compared to Examples 1, 2 and 5 of the invention. This argument is not convincing because it is not clear whether the comparative example is representing the composition recited in the instant claims. Specifically, Examples 1, 2, and 5 do contain waxes, but also contain several other different components and/or weight percentage ranges of components that may influence the overall stability of the compositions. Furthermore, it is clearly taught in the prior art, that adding a wax to the oily phase of an o/w emulsion increases the viscosity, and thereby the stability of the composition. Thus, Applicants' arguments are not found persuasive.

***Response to Affidavit***

10. The remarks and evidence in the declaration under 37 CFR 1.132 filed 3/5/2008 have been carefully considered and are not found persuasive to overcome the rejection of claims 1-17 based on the new grounds of rejection as set forth above.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the evidence present is not of a scope reasonably commensurate with the scope of the subject matter claimed. Only one specific comparative example is provided as evidence, which does not provide sufficient evidence that the remaining composition formulations possible under the claim scope would exhibit the same or similar results as presented in the table on page 2-3 of the declaration. It is also noted that Morschäuser et al. does teach an o/w emulsion that comprising an AMPS polymer that is within the scope of the instant claim 1 (see column 11, Example 2, and Example 41, columns 18-19). Thus, it is known in the prior art to employ an AMPS polymer with less than 25 oxyethylene groups in an o/w emulsion, contrary to what is stated on page 3, bullet 9 of the declaration. Therefore, no clear and

convincing unexpected benefit is seen to be present herein. Thus, the instant claims are still considered properly rejected under 35 USC 103(a).

### ***Conclusion***

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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JLK

/San-ming Hui/  
Primary Examiner, Art Unit 1617